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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,334	04/02/2004	Bruce D. Hammock	02307W-131010US	1147

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,334	HAMMOCK ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60 and 70-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60 and 70-105* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration, the previous restriction requirement, mailed November 29, 2005, is withdrawn in favor of the instant requirement.

Claims 1-60 and 70-105 are pending and require restriction. Please note, claim 72 has not been included in any group as it depends from a cancelled claim.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 58-60, 70, 71 and 95-105, drawn to compounds of formula (I), classified in class 526, subclass 280.

II. Claims 59 and 71, drawn to compounds of formula (II), classified in class 514, subclass 2.

III. Claims 1-17, drawn to a method for inhibiting a soluble epoxide hydrolase with compounds of formula (I), classified in class 526, subclass 280.

IV. Claims 1-17, drawn to a method for inhibiting a soluble epoxide hydrolase with compounds of formula (II), classified in class 514, subclass 2.

V. Claims 18-29, drawn to methods of treating diseases modulated by soluble epoxide hydrolase with compounds of formula (I), classified in class 526, subclass 280.

VI. Claims 18-29, drawn to methods of treating diseases modulated by soluble epoxide hydrolase with compounds of formula (II), classified in class 514, subclass 2.

VII. Claims 30-35, drawn to methods of treating or reducing renal deterioration in a patient with compounds of formula (I), classified in class 526, subclass 280.

VIII. Claims 30-35, drawn to methods of treating or reducing renal deterioration in a patient with compounds of formula (II), classified in class 514, subclass 2.

IX. Claims 36-39, drawn to a method for inhibiting progression of nephropathy in a subject with compounds of formula (I), classified in class 526, subclass 280.

X. Claims 36-39, drawn to a method for inhibiting progression of nephropathy in a subject with compounds of formula (II), classified in class 514, subclass 2.

XI. Claims 40-45, drawn to methods for reducing blood pressure in a subject with compounds of Formula (I), classified in class 526, subclass 280.

XII. Claims 40-45, drawn to methods for reducing blood pressure in a subject with compounds of Formula (II), classified in class 514, subclass 2.

XIII. Claims 46 and 47, drawn to methods of inhibiting the proliferation of vascular smooth muscle in a subject with compounds of Formula (I), classified in class 526, subclass 280.

XIV. Claims 46 and 47, drawn to methods of inhibiting the proliferation of vascular smooth muscle in a subject with compounds of Formula (II), classified in class 514, subclass 2.

XV. Claims 48-57, drawn to methods of inhibiting the progression of obstructive pulmonary disease, an interstitial lung disease, or asthma in a subject, with compounds of Formula (I), classified in class 526, subclass 280.

XVI. Claims 48-57, drawn to methods of inhibiting the progression of obstructive pulmonary disease, an interstitial lung disease, or asthma in a subject, with compounds of Formula (II), classified in class 514, subclass 2.

XVII. Claim 73-81, drawn to methods for stabilizing biologically active epoxides in the presence of a soluble epoxide hydrolase with compounds of Formula (I), classified in class 526, subclass 280.

XVIII. Claim 73-81, drawn to methods for stabilizing biologically active epoxides in the presence of a soluble epoxide hydrolase with compounds of Formula (II), classified in class 514, subclass 2.

XIX. Claim 82-90, drawn to methods for reducing the formation of a biologically active diol produced by the action of a soluble epoxide hydrolase with compounds of Formula (I), classified in class 526, subclass 280.

XX. Claim 82-90, drawn to methods for reducing the formation of a biologically active diol produced by the action of a soluble epoxide hydrolase with compounds of Formula (II), classified in class 514, subclass 2.

XXI. Claim 91-94, drawn to methods for monitoring the activity of a soluble epoxide hydrolase with compounds of Formula (I), classified in class 435, subclass 4.

XXII. Claim 91-94, drawn to methods for monitoring the activity of a soluble epoxide hydrolase with compounds of Formula (II), classified in class 435, subclass 4.

The inventions are independent or distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as

claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the structures of the two generic formulae (I) and (II) do not overlap in scope and are not obvious variants, as formula (II) requires amino acids be present and does not have L^2 or P^2 and/or P^3. As such, the compounds would be expected to have a different mode of operation and/or effect.

Inventions I and III, V, VII, IX, XI, XIII, XV, XVII, XIX and XXI are related as product and process of use. Inventions II and IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX an XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case as evidenced by the claims themselves, one can practice the methods with a myriad of distinct compounds, and one can use the compounds in various methods.

Further, one could inhibit sEH with diuron; one could treat a disease modulated by sEH, e.g. arthritis, with prednisone; one could treat renal deterioration with lanapril; one could inhibit the progression of nephropathy with N-(3,4-dimethoxycinnamoyl) anthranilic acid; one could reduce blood pressure, with furosemide; one could inhibit the proliferation of vascular smooth muscle with estrogen; one could inhibit the progression of asthma with fluticasone; one could stabilize biologically active epoxides and reduce the formation of diol with diuron; one could monitor the activity of sEH with diuron.

Inventions III and IV; V and VI; VII and VIII; IX and X; XI and XII; XIII and XIV; XV and XVI; XVII and XVIII; XIX and XX; and XXI and XXII are directed to related methods of use within each respective pair (e.g. III and IV). The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods use compounds which are independent or distinct, one from another, and in practicing the method with one, one would not be practicing the other.

Inventions II and III, V, VII, IX, XI, XIII, XV, XVII, XIX and XXI are unrelated. Inventions I and IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX and XXII are unrelated. Inventions III and IV and Inventions V and VI and Inventions VII and VIII and inventions IX and X and Inventions XI and XII and Inventions XIII and XIV and Inventions XV and XVI and Inventions XVII and XVIII and Inventions XIX and XX and Inventions XXI and XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Group I are not used in the method of Groups IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX and XXII, and the products of Group II are not used in the methods of Groups III, V, VII, IX, XI, XIII, XV, XVII, XIX and XXI, and in practicing one method one would not be practicing another. Further, in practicing the method of one invention (e.g. III or IV) one would not necessarily be practicing another (e.g. VII or VIII).

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Additionally, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making. Because these inventions are independent or distinct for the reasons given above, the inventions require a different field of search (see MPEP § 808.02) and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Claims 1-60, 70, 71 and 73-105 generic to the following disclosed patentably distinct species: The claims are generic to a myriad of compounds, including the compounds of Tables 1-15 and 17. The species are independent or distinct because the compounds are structurally distinct and the search of one compound would not necessarily lead to the discovery of another. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Please note, a single species is a single compound, e.g compound 790.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADK

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